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| 10/564,564 | 06/14/2006 | Fujihiko Tomita | 90606.87/ok | 2014 |
| 54071 | 7590 | 05/28/2009 | EXAMINER | |
| YAMAHA HATSUDOKI KABUSHIKI KAISHA C/O KEATING & BENNETT, LLP 1800 Alexander Bell Drive SUITE 200 Reston, VA 20191 | | | HENKEL, DANIELLE B | |
| | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/564,564 | TOMITA ET AL. | |
| | Examiner | Art Unit | |
| | DANIELLE HENKEL | 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 05 February 2009.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 17-27,30,31 and 37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 17-27, 30-31, 37 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed February 5, 2009 has been entered and fully considered.
2. Claims 17-27, 30-31, and 37 are pending.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 17, 23, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over ASHIHARA (JP 06-153902) in view of TERENTIEV (WO 2005/068059).

a. With respect to claim 17, ASHIHARA teaches a device for culturing microorganisms with a culture medium in a culture bag (container) with the culture tank held by a supporter material (Paragraphs 0001, 0004). ASHIHARA teaches the culture bag is flexible and in a folded state during storage but it hangs inside the supporter material when in use (Paragraph 0006). ASHIHARA does not explicitly disclose the container takes on and maintains a predetermined shape defined by the support such that it repeatedly occupies an identical space within the support. However, TERENTIEV teaches a microorganism culturing apparatus with a container (bag) that takes on and maintains a predetermined shape defined by a support such that the container repeatedly occupies an identical space within the support (Page 8, lines 2-9). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of ASHIHARA to include the container takes on a predetermined shape defined by the support and repeatedly occupies an identical space as taught by TERENTIEV because it allows for the use of a disposable, flexible bag as culture vessel in which traditional bioreactor components can be provided, the structure also making it easier to maintain exact culture conditions by always maintaining the same shape (Page 2, lines 12-Page 3, line 3).

b. With respect to claim 23, ASHIHARA teaches a gas introduction pipe inserted through the lid of the culture bag (Paragraph 0006).

c. With respect to claim 30, ASHIHARA teaches a gas introduction pipe (substantially circular) that is porous and the culture bag has an opening in only

one position which provides access to the inside of the bag (Paragraph 0006). A tube extends through the opening of the culture bag of ASHIHARA with one end connected to the gas introduction pipe and the other end exterior to the bag to allow the supply of gas (Paragraph 0004 and Drawing 1).

d. With respect to claim 31, ASHIHARA teaches the culture tank is a flexible bag shown to have longer and shorter sides (substantially rectangular) with the open portion at one of the shorter sides having a through hole (shaft passage member) which one end of the gas introduction tube extends outward through with the remainder of the tube (shaft passage member) descending along the long side of the bag (Drawing 1).

6. Claims 18-20, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over ASHIHARA (JP 06-153902) in view of TERENTIEV (WO 2005/068059) as applied to claims 17, 23, 30, and 31 above, and further in view of OTSUKI (JP 2000-139444).

a. With respect to claim 18, ASHIHARA teaches the culture bag (container) is transparent (Paragraph 0006), but does not explicitly disclose the support having a bottom and side plates. However, OTSUKI teaches a culturing apparatus that has a pair of transparent plates supported by the lower manifold (bottom) of a frame-like supporter material (Paragraph 0027). As both the culture container of ASHIHARA and the side plates of OTSUKI are transparent the transparent portions of both will overlap. At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of

ASHIHARA with the support of OTSUKI having the side plates and bottom because it allows for the creation of a culture space that can be sealed with the sides mutually supported and the transparency allows for light to penetrate allowing the culture to grow (Paragraphs 0006-0007).

b. With respect to claim 19, OTSUKI teaches the plates are parallel with a culture space between (oppose each other) (Paragraph 0027). Drawing 6 also further depicts the plates as flat and opposing.

c. With respect to claim 20, OTSUKI teaches side plates attached to a manifold of frame-like supporter material at the top and bottom portions of the plates using a nut and bolt screw system (removably fixed) (Paragraphs 0027 and 0028) because it allows for easy assembly and removal of the apparatus (0019).

d. With respect to claim 37, ASHIHARA does not explicitly disclose the support includes a framework. However, OTSUKI teaches the support includes a framework, a plurality of the containers, a first plurality of side plates disposed end to end in the longitudinal direction of the framework, and a second plurality of side plates disposed end to end in the longitudinal direction and parallel to the first plurality of side plates, wherein the plurality of the containers are arranged between the first plurality of side plates and the second plurality of side plates, respectively, and the culturing apparatus contains no other side plates other than the first plurality of side plates and the second plurality of side plates (0026-0027). At the time of the invention it would have been obvious to one of ordinary

skill in the art to modify the apparatus of ASHIHARA with the support of OTSUKI having the framework and plurality of containers because it allows for the creation of a culture space with the sides mutually supported, the transparency allows for light to penetrate allowing the culture to grow, and the multiple reactors allows for a single light to be efficiently reflected and scattered into the reactor modules (Paragraphs 0006-0007, 0021).

7. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over ASHIHARA (JP 06-153902) in view of TERENTIEV (WO 2005/068059) as applied to claims 17, 23, 30, and 31 above, further in view of OTSUKI (JP 2000-139444) as applied to claims 18-20 above, and further in view of FOX (US 6942775).

a. With respect to claim 21, the combination of ASHIHARA and OTSUKI teaches the culturing apparatus of claim 20, but does not explicitly disclose posts and pressing members. However, FOX teaches a frame assembly with a platform style base having vertical members (posts) extending to a cover of the frame. FOX also teaches clamps (pressing members) attached along the members to hold a plate against the frame (Column 5, lines 20-55). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the frame of ASHIHARA and OTSUKI to include the posts and pressing members as taught by FOX because it allows for the plates to be removably held in place for ease of setup and use as with the device of ASHIHARA as modified by OTSUKI.

b. With respect to claim 22, ASHIHARA in view of OTSUKI teaches the culture units are arranged end to end with plates sharing a mutual frame (Paragraph 0027), but the combination of ASHIHARA and OTSUKI does not explicitly disclose the plates interconnected through the posts. However, FOX teaches the vertical posts with clamps as pressing members. It would have been obvious to one of ordinary skill in the art to combine the culturing modules sharing a mutual frame ASHIHARA and OTSUKI to include the clamp fixing the plates to a post as taught by FOX because the clamping mechanism allows for ease in manufacturing and set up of the removably fixed plates.

8. Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over ASHIHARA (JP 06-153902) in view of TERENTIEV (WO 2005/068059) as applied to claims 17, 23, 30, and 31 above, and further in view of OTSUKI (JP 2000-139444) as applied to claims 18-20 above, and further in view of WATERHOUSE (US 6005663).

a. With respect to claim 24, the combination of ASHIHARA and OTSUKI does not explicitly disclose the side plates supported for rotation about the bottom ends. However, WATERHOUSE teaches a chamber in which the front side forms an access door which is hinged at the bottom (supported for rotation) to allow release from the frame of the chamber (Column 9, lines 22-27). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the culture apparatus of ASHIHARA and OTSUKI to include the plates being able to rotate open as taught by WATERHOUSE because it permits

movement from a closed position to an open position to allow access to the chamber (Column 9, lines 22-27).

b. With respect to claim 25, the combination of ASHIHARA, OTSUKI, and WATERHOUSE teaches the claimed invention except for the wires connecting the plates to the framework. It would have been obvious to one of ordinary skill in the art at the time of the invention to include the wires as using wires to allow a rotation range of the plates is equivalent to using a hinge to allow the plates to rotate as in WATERHOUSE. (MPEP 2144.06)

c. With respect to claim 26, WATERHOUSE teaches the hinged panel has a rotation range from closed to opened until the panel contacts the bottom of the frame where it is stopped (Figure 9A).

d. With respect to claim 27, WATERHOUSE teaches the panel rotates from a closed position (attachment) to an open position (released) in which the top of the panel is rotated clear of the top of the device allowing an access space between the frame of the device and the panel (Column 9, lines 22-27, Figure 9A).

Response to Arguments

9. Applicant's arguments with respect to claims 17-27, 30-31, and 37 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE HENKEL whose telephone number is (571)270-5505. The examiner can normally be reached on Mon-Thur: 11am-8pm, Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/DANIELLE HENKEL/
Examiner, Art Unit 1797